UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,188	09/17/2003	Satoru Iguchi	PC25301A	8576

28523 7590 06/25/2004

PFIZER INC.
PATENT DEPARTMENT, MS8260-1611
EASTERN POINT ROAD
GROTON, CT 06340

EXAMINER	
HUANG, EVELYN MEI	
ART UNIT	**PAPER NUMBER**
1625	

DATE MAILED: 06/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/667,188	IGUCHI ET AL.	
	Examiner	Art Unit	
	Evelyn Huang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-12 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-12 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-12 are pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 11 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant method for the treatment or prevention of disease conditions mediated by 5-HT4 receptor activity reaches out to as yet unidentified diseases/conditions/activities, the description of which is not found in the specification. The mediation of 5HT4 receptor involves agonism, antagonism and others, which leads to opposing and conflicting conditions/disorders. A full description of the treatment or prevention of disease conditions mediated by any 5-HT4 receptor activity is not found in the specification.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in

the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. ***.

a. *Nature of the invention.*

The instant invention is drawn to a imidazo[1,2-a]pyridine compound and its method of treating or preventing a disease condition mediated by 5-HT4 receptor activity, the specific diseases are recited on pages 1-2 of the specification.

b. *State of the prior art and the level of the skill in the art.*

The 5-HT4 receptors, and some of the agonists and antagonists thereof, are reviewed by Eglen (PTO-1449). The diseases or conditions requiring a 5-HT4 agonist are shown to be distinct from those requiring a 5HT4 antagonist. A nexus between the activation or inhibition of 5-HT4 receptors and the treatment or prevention of any or all of these diseases have not been fully established (Barnes et al. Neuropharmacology 38(1999) 1083-1185, 1118-1125). For example, while a number of reports have indicated the activation of 5-HT-4 receptors facilitates cognitive performance (and a 5HT4 agonist would be indicated), there are currently no reports concerning whether selective 5-HT4 receptor ligands modify cognitive performance in man. While 5-HT4 receptor is implicated in anxiety (wherein an 5-HT4 antagonist would be indicated), there is apparent disagreement regarding the precise role that the 5-HT4 receptor plays (Barnes, page 1123-1124).

While some the recited disease may be treatable, the prevention of these diseases is not feasible as the criteria to predict the subjects at risk of having these diseases have not been established.

The level of the skill in the 5-HT4 receptor ligand art is high.

c. *Predictability/unpredictability of the art.*

The high degree of unpredictability is well recognized in the 5-HT receptor ligand art. A slight change in the structure of the compound would drastically alter its affinity and selectivity (Lopez-Rodriguez et al. Bioorganic & Medicinal Chemistry 7(1999) 2271-2281, PTO-1449, pages 2273-4, Tables1-2).

d. *Amount of guidance/working examples.*

Preparation of example compounds has been described.

The procedures for the 5-HT4 receptor binding assays are described on pages 23-26 while the procedures for agonist-induced cAMP elevation in transfected HEK383 cells and the I_{HERG} assay are described on pages 26-79 of the specification. The results for the example compounds are found on pages 29-30 of the specification. No in vivo procedures are described.

e. *The breadth of the claims.*

Applicant's assertion that the inventive compounds would be effective in treating or preventing any disease condition mediated by 5-HT4 receptor activity (including the as yet unidentified diseases/conditions, the conflicting and/or opposite conditions treatable only with an antagonist or an agonist, the myriads of diverse disorders/diseases within the central nervous system, or any of the neurological diseases of different origins), does not commensurate with the scope of the objective enablement, especially in view of the high degree of unpredictability in the art and the limited working examples (paragraphs b, c, d above).

f. *Quantitation of undue experimentation.*

In view of the high degree of unpredictability in the art, the limited working examples and the fact that the breadth of the claims does not commensurate with that of the objective enablement, the disclosure as presented would not allow one of ordinary skill in the art to use the invention as claimed without undue experimentation (paragraphs b-e above), especially when the nexus between the activation or inhibition of 5-HT4 receptors and the treatment or prevention of any or all of these diseases have not been fully established

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Uchida (6624162).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Uchida's Examples 26, 28-30 (columns 46, 49, 50, 52), the composition and method of use thereof, are encompassed by the instant claims 1-3, 10-12. Uchida's Examples 26, 28-30 are identical to the compound of instant claims 5-9 respectively.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 8-11 of U.S. Patent No. 6624162. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant compound is encompassed by the patented claims; more specifically, the compounds of instant claims 5-9 are identical to the preferred example compounds within the patented genus.

One of ordinary skill in the art would be motivated to select the preferred compounds within the genus to arrive at the instant invention.

7. Claims 1-12 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the corresponding claims of copending Application No. 10/617920 (division of 6624162). Although the conflicting claims are not identical, they are not patentably distinct from each other because of the reasons set forth in the above paragraph 6.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

8. No claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Evelyn Huang
Primary Examiner
Art Unit 1625